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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,493	06/22/2001	Gregor Cevc	500.1013	7718

7590 06/17/2003

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EXAMINER
COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary Examiner Susan Coe 1654 The MAILING DATE of this communication appears on the cover sheet with the correspondence addres Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b) Status 1) Responsive to communication(s) filed on 03 April 2003. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the macclosed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims	
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Disposition of Claims	,, no 10
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4) Claim(s) 1-7,9,11-14,21-24,35,39-41,44-46 and 51-82 is/are pending in the application.	
4a) Of the above claim(s) <u>52,53,55-75 and 77-82</u> is/are withdrawn from consideration.	
5) Claim(s) is/are allowed.	
6) Claim(s) 1-7, 9, 11-14, 21-24, 35, 39-41, 44-46, 51, 54, and 76 is/are rejected.	
7) Claim(s) is/are objected to.	
8) Claim(s) are subject to restriction and/or election requirement. Application Papers	
9) The specification is objected to by the Examiner.	
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.	
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).	
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.	
If approved, corrected drawings are required in reply to this Office action.	
12) The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. §§ 119 and 120	
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).	
a) ☐ All b) ☐ Some * c) ☐ None of:	
1. Certified copies of the priority documents have been received.	
2. Certified copies of the priority documents have been received in Application No	
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 	е
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional app	lication).
 a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 	
Attachment(s)	
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	

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DETAILED ACTION

- 1. The amendment filed January 11, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
- 2. Claims 26-34, 36-38, and 47-50 have been cancelled.
- 3. Claims 51-82 have been added.
- 4. Claims 1-7, 9, 11-14, 21-24, 35, 39-41, 44-46 and 51-82 are pending.
- 5. In Paper No. 9, dated October 10, 2002, applicants elected a cellulose derivative for species A, BHT for species B, methylparaben for species C, and clobestasol for species D without traverse.
- 6. Claims 52, 53, 55-75 and 77-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.
- 7. Claims 1-7, 9, 11-14, 21-24, 35, 39-41, 44-46, 51, 54, and 76 are examined on the merits.

Claim Rejections - 35 USC § 102

8. Claims 1, 7, 11, 12, 14, 21-24, 35, 41, 46, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by German Pat. No. 44 47 287 C1 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that DE '287 does not teach adding the active agents at about 0.1 weight percent relative to the total dry mass of the formulation. However, on pages 46 and 48, DE '287 teaches adding active agents such as Diclofenac and

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Ibuprofen in amounts that greatly accede 0.1%. In addition, the reference states that the active agent is present in amounts up to 15% by weight depending on the solubility of the active agent (see page 25). Therefore, adding the active agents in the claimed amounts to the carrier system taught by the reference is clearly taught by the reference.

Claim Rejections - 35 USC § 103

9. Claims 1-7, 9, 11-14, 21-24, 35, 39-41, 44-46, 51, 54, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over German Pat. No. 44 47 287 C1 in view of US Pat. No. 5,322,685 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that a person of ordinary skill in the art would not be motivated to modify DE '287 based on US '685 because US '685 is directed towards a different type of topical formulation. However, US '685 addresses similar problems to those identified by DE '287. DE '287 uses consistency builders and preservatives (see page 25) as does US '685 (see column 3, lines 52-61). Therefore, since the problems of both references are the same, a person of ordinary skill in the art would reasonably look to the references to correct the problems.

In addition, applicant argues that DE '287 only teaches the use of steroids as test agents. However, DE '287 clearly states that numerous active agents, including corticosteroids, can be included in the transferosome carrier (see pages 23 and 24). The reference specifically states that the active agent is present in amounts up to 15% by weight depending on the solubility of the active agent (see page 25).

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Therefore, based on the teachings of the references, applicant's claims are still considered to be obvious based on the combination of DE '287 and US '685.

10. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner June 12, 2003

LEON B. LANKFORD, JR. PRIMARY EXAMINER